Comparison of clinical outcomes of radioactive seed versus wire localisations.

Purpose:

The purpose of this study was to compare clinical outcomes of radioactive seed versus wire localisations in evaluation of vasovagal episodes, wires and seed migration, and rate of positive margins.

Materials and Methods:

Severity of vasovagal episodes, degree of migration and probable causes for margin positivity were assessed in all patients of wire (1145) and seed (180) localisations since 2012. Success of localization procedure was based on radiological as well as pathological end points. Final outcome parameters for those with severe vasovagal episodes were, (i) need for multiple seed/ supplemental wires, (ii) delays/rescheduling subsequent surgery, (iii) additional margins/re-excision and (iv) additional post-operative imaging to assess residual disease. It was hypothesized that patients were predisposed to greater risk of vasovagal episodes on the day of the surgery owing to higher anxiety level and fasting status. Information about pain scale and level of satisfaction was retrieved from patient surveys.

Results:

Preliminary results of prospective implementation of the radioactive seed localisation program found 1 severe vasovagal reaction in 180 localisations (0.56%, mammographically-guided), performed during a 6-month period. Retrospective analysis of severe vasovagal episodes during wire localisation showed comparable incidence of 0.52% (6/1145), 4 with mammographic and 2 with ultrasound guidance. Four of the 6 wire localisations were technically successful despite being complicated by vasovagal episodes and showed no adverse outcome. Onset of pre-syncope was more common (4/7 patients) in pre-deployment phase of the localisation. In 33% (2/6) patients, severe vasovagal episodes resulted in clinically important wire migrations leading to positive margins and surgical revisions. Patients rated lower pain scores as well as higher overall satisfaction for seed localisations than those who had wire localisations. The data for the rate of positive margins is being evaluated concurrently and will be compared between the wire and seed localisations.

Conclusion:
Rate of vasovagal episodes of radioactive seed localisation program remained comparable to wire localisations despite the initial learning curve. No migrations were reported with seed localisations. Patient satisfaction and pain were markedly improved with seed localisations.

Clinical relevance:

The rate and outcome of vasovagal reactions has not been well evaluated in breast localisations. Although a relatively infrequent complication, vasovagal reactions during preoperative localisation often interfere with operating room efficiency and final surgical outcome, particularly at high volume centers.

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Initial Experience with Upright Tomosynthesis and Stereotactic Core Biopsy in a Community Breast Center

Clinical Relevance:

Vacuum-assisted prone stereotactic core biopsy is the most common diagnostic procedure for mammography-only detected lesions, however is not always feasible due to patient and technical factors. In such cases, upright biopsy may be a successful alternative, thereby avoiding surgery, with the additional benefit of shorter procedure times.

Purpose:

The purpose of this study is to evaluate procedural time and clinical performance of upright tomosynthesis and stereotactic core breast biopsy compared to traditional prone positioning. Data collection is ongoing, with intent to have a larger sample at presentation time.

Materials & Methods:

Upright tomosynthesis and stereotactic core biopsy was recently implemented at San Francisco General Hospital. Results from twenty-one consecutive patients in each group (upright versus prone) performed between March and November, 2015 were reviewed. One upright patient had bilateral biopsies (N=22). All biopsies were performed using a standard 9-gauge needle connected to a vacuum-assisted core biopsy device with an average of 12 core samples taken. Evaluation criteria were indication, histopathology, technical feasibility, complications, and procedural time. Procedural time was assessed
using overall time (from first acted-upon image until last image), and needle time (from first image showing needle in breast until last image). Data was analyzed using an independent samples t-test after log or square transformation.

Results:

Technical success was ultimately achieved in all cases. There was one complication in the upright group (mild vasovagal response) and none in the prone group. Architectural distortion was a more frequent indication for upright biopsy (6/22 versus 0/21), all performed with tomosynthesis guidance, and yielded malignancy or high-risk lesions in 50% (3/6). Remaining indications were otherwise similar. Histopathology from the two groups had a similar distribution of benign, high-risk, and malignant lesions.

Reason for upright biopsies included: failed prone biopsy (6), tomosynthesis-only finding (7), incorrect ultrasound correlate (2), subtle lesion (2), limited patient mobility (2), and unspecified (3). Prone biopsy failure occurred due to: breathing difficulty (2), back pain (1), and poorly visualized/posteriorly located lesion (3/6). All six patients subsequently underwent successful upright biopsy, and 83% (5/6) yielded benign pathology, thereby avoiding surgical excisional biopsy.

Differences in overall procedure and needle time were statistically significant: 17.5 minutes upright, 21.6 minutes prone (p=.017) and 6.8 minutes upright, 9.3 minutes prone, (p=.007) respectively.

Conclusion:

Upright core biopsy may be successfully performed after a failed prone attempt and also allows sampling of tomosynthesis-only detected lesions. Shorter procedure times may improve patient experience and throughput.

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Radiologic-Pathologic Discordance and Outcome After MRI-Guided Vacuum Assisted Biopsy (VAB)

Purpose: The purpose of this study is to determine outcomes of discordant MRI guided vacuum-assisted biopsy.

Materials and Methods: This IRB approved HIPAA compliant retrospective study reviewed 7204 breast MRI exams performed 2007-2013 to identify MR-9G-VAB that were assessed as discordant after biopsy.
Initial and final surgical pathology was reviewed along with MR imaging characteristics of the discordant lesions. We reviewed MR imaging to determine whether discordant lesions were still present after biopsy (i.e. missed, partially sampled, or completely excised). Statistical analysis was performed using the Fischer’s exact test.

Results: We identified 1211 women with 1314 lesions detected at MRI and biopsied under MRI guidance. 2% (25/1314) lesions were discordant and 36% (9/25) were found to be malignant after surgical excision (DCIS, n=6; IDC, n=3). There was a trend (p=0.071) towards an association between whether a lesion was subsequently malignant among cases with a clinical indication of newly diagnosed cancer. There was no significant association between whether a lesion was cancer on surgical excision and lesion size, lesion type, internal enhancement or kinetic curve. Of all discordant lesions, 44% (11/25) lesions were missed, 40% (10/25) lesions were partially sampled, and 16% (4/25) lesions were excised. Neither lesion morphology nor size was predictive of a lesion being missed. Pathology was mixed in the missed cases with 4 final excisions yielding benign findings, 3 high risk lesions, and 4 cancers. There was also one case of stable findings on one year follow-up MRI without surgical pathology. Of discordant cancers, median size was 13 mm (range 6-20 mm). 78% (7/9) lesions were masses and 22% (2/9) presented as NME. Four cancers were sampled, four were missed, and one was excised at MR biopsy. In 22% (2/9) cases, biopsy change obscured the lesion and in 56% (5/9 cases), normal enhancing tissue obscured the area.

Discussion: Discordance was found in 2% of lesions undergoing MR VAB. 36% of all discordant lesions were found to be malignant, higher than the malignancy/discordant rate for US and stereotactic guided biopsies. Our findings demonstrate the importance of radiologic-pathologic correlation and review.

Clinical Relevance: Radiologic-pathologic correlation is essential after MR-biopsy. The high percentage of malignancies after discordance demonstrates the importance of repeat biopsy or surgical excision in this setting.

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Savi Scout Surgical Guidance System for non-palpable breast lesion localization and excision: A Feasibility Study

Purpose: To evaluate the feasibility of the Savi Scout Surgical Guidance System for the localization and surgical excision of nonpalpable breast lesions.
Materials and Methods: An IRB approved HIPAA compliant retrospective review of 15 Savi Scout Surgical Guidance System (Savi Scout ®, Cianna Medical) cases was performed. An FDA approved non-radioactive, infrared-activated, electromagnetic wave reflective device (reflector) was percutaneously inserted by a breast radiologist adjacent to/within 15 non-palpable breast targets in 13 patients utilizing image guidance. Post-procedure mammogram and percutaneous detection confirmed reflector placement and function. Target/reflector were surgically excised utilizing an electromagnetic wave/infrared light emitting system which receives a reflected signal allowing surgeon localization. Target/reflector removal was verified with handpiece specimen interrogation, specimen radiography and pathologic analysis. Distance between target and reflector on mammogram and specimen radiograph was recorded in addition to reflector distance from the skin. Final specimen pathology including margins was reviewed.

Results: 15/15 (100%) reflectors were placed within the breast under image guidance, 8/15 utilizing ultrasound and 7/15 mammogram guidance (0.2 cm mean target-reflector distance on post-biopsy mammogram). 15/15 (100%) targets/reflectors were excised utilizing Savi Scout. Final pathology yielded 5 malignancies (0.5-1.2 cm; 1 IDC, 1 ILC, 2 DCIS, 1 papillary ca) all with negative margins, 5 high risk lesions (2 ALH, 3 papillomas) and 5 benign concordant results. 14/15 (93%) specimen radiographs demonstrated a target-reflector distance compared with post-procedure mammogram obtained the day of reflector placement within 0.3 cm. 1/15 (7%) specimen demonstrated a 2.7 cm increased target-reflector distance on specimen radiograph compared with post-procedure mammogram (reflector in a large post-biopsy hematoma). Average reflector depth on post-procedure mammogram was 2.4 cm (range 1.2-3.7 cm) and 1.0 cm (range 0.5-2.5 cm) on ultrasound. No procedural or related post-operative complications were identified. No patients required re-excision. Observed benefits included OR scheduling flexibility, independent radiologist and surgeon procedure approach, reflector provided point source for continuous reorientation in the OR and no radioactive safety precautions necessary.

Conclusion: The Savi Scout is a feasible method to localize and excise nonpalpable breast lesions and appears to overcome many limitations associated with wire and I-125 seed localization warranting further study.

Clinical Relevance: Excision of non-palpable breast lesions utilizing a guidewire has numerous disadvantages recently overcome with I-125 radioactive seed localization. Savi Scout provides a feasible non-radioactive alternative with OR scheduling efficiency, no risk of wire displacement/transection, independent radiologist and surgeon procedure approach optimization and reflector point source for orientation in the OR.

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Minimally-invasive, Sutureless, Stereo-targeted Definitive Lumpectomy in the Imaging Suite

Purpose: Definitive management of DCIS and small cancers in the imaging suite to minimize discomfort and cost.

Materials and Methods: 94 women ages 31-86 had removal of small DCIS and invasive cancers using a 20mm radiofrequency basket-capture with stereotactic guidance. Tissue elasticity permitted removal through a 12mm incision. A second 20mm basket-capture was used to obtain shaved margins. Incisions were closed with Steri-Strips™. Procedures were conducted under local anesthesia and with P.O. sedation in the imaging department. Patient tolerance scores were recorded. Standard radiologic evaluation (specimen and breast) and histologic criteria were applied in all cases. Patient data are registered prospectively and reported with informed consent.

Results: Final histologic size ranged from 1-20 mm. Of 40 DCIS and 54 Invasive lesions, 18 (19%) had positive margins and/or open re-excision including one patient who had re-excision in spite of negative margins because of inadequate shaved-margin quality (no residual disease on pathology). 74 patients went on to complete accelerated partial (58) or whole breast (16) radiation. Patient pain scores averaged 1.9 out of 10 (range 0-7).

Conclusion: For small DCIS and invasive cancers, image guided, minimally-invasive lumpectomy can be accomplished in the imaging suite. The intact specimen permits standard of care histologic analysis of lesions and margins. Because stereo targeting requires less tissue removal via small incisions that do not require sutures, image guided lumpectomy reduces morbidity, distress, discomfort and expense associated with overtreatment of small breast cancers. This opens an opportunity for imaging specialists, who provide surveillance for these patients long term, to assist in actively treating small cancers.

Clinical relevance statement: Despite advances in technologies characterizing breast cancer biology, indolent lesions cannot be identified. Many indolent breast cancers and DCIS are over-treated to avoid under treatment of life threatening cancers. Improving use of specialty resources to reduce overtreatment meets a high priority need in modern breast cancer care.

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Frozen section evaluation in breast core biopsy: feasibility and concordance with routine pathology

Purpose:

To explore the feasibility of rapid frozen section evaluation in breast core biopsy and the rate of concordance with routine permanent section pathology.

Materials and Methods

Twenty-six patients were selected from a group of patients undergoing ultrasound (US) guided core needle biopsy of breast masses between January 2014 and August 2015. Selection criteria were: women aged 30 years and older with masses highly suggestive of malignancy (BI-RADS 5) on US. Core biopsy was performed using a 14-gauge automated spring-loaded needle. A single core was placed in saline for frozen section, and the remaining 2 or 3 cores in 10% formalin for routine processing. In one case that was ultimately proven to be mucinous carcinoma on routine pathology, core tissue fragmentation precluded frozen section, and the case was excluded from the analysis. All cores were delivered to the pathology lab within 5 minutes of tissue harvesting.

Specimens for frozen section were grossed and placed in CryoPrep mounting media at -21 degrees Celsius. Tissue was sectioned at 5 micron intervals in a Thermo Scientific cryostat. Slides were prepared using a modified Hematoxylin and Eosin stain, coverslipped and examined. Specimens for permanent section were processed in the usual fashion.

Results

Twenty-five patients comprised the study group. The age ranged from 40 to 85 years (median, 59). Frozen section pathology in 23 out of 25 cases was invasive carcinoma. One case was benign and one atypia. Pathologist’s assessment of core tissue used for frozen section was “adequate” in all cases. Turnaround time for frozen section results was between 15 and 20 minutes. There was 100% concordance with routine pathology, which demonstrated invasive ductal carcinoma (IDC) in all cancer cases (21 cases of IDC NOS, 1 case of papillary and 1 case of mucinous IDC). The benign case had xanthogranulomatous inflammation on frozen and routine pathology and therefore concordant. The atypia case was atypical papillary lesion on frozen and routine pathology (concordant) and ultimately proven invasive papillary carcinoma on excision.

Conclusion

Frozen section evaluation in US guided breast core biopsy of masses in a carefully selected population is feasible and accurate.

Clinical Relevance
Frozen section evaluation in breast core biopsy reduces the time it takes to get the initial pathology result from the usual 2 days to 20 minutes and has the potential to reduce patients’ anxiety of waiting for biopsy results.

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Patient-Centered Breast Imaging Consultation Services: Opportunities to Engage Patients and Add Value to Their Care

Purpose:
To assess patients’ interest in additional services at an outpatient breast imaging center, including discussion of imaging results and breast density, assessment of breast cancer risk status, and performance of clinical breast exam (CBE).

Methods:
An anonymous survey was distributed to women presenting for screening or diagnostic mammography at an outpatient academic breast imaging center, and to date, data from 559 women have been collected. Patients were asked about their interest in: discussion of imaging results, breast density, and breast cancer risk status; performance of CBE; knowledge of breast density; provider preference; and willingness to pay consultation fees for a breast radiologist.

Results:
Most women are interested in discussing imaging results (65.7%), determining breast cancer risk status (63.6%), and having an informed discussion on breast density (67.4%), despite 57.5% of women feeling they understand the concept of breast density. Women preferred to meet with breast radiologists for these discussions regarding imaging results (66.7%), breast density (61.4%), and risk status assessment (55.5%). Fewer patients (49.9%) were interested in a CBE, but of those, 49.1% prefer a breast radiologist, 42.7% prefer a nurse practitioner, and 8.2% have no preference. Only 26.0% of patients were willing to pay a consultation fee for a breast radiologist.

Conclusion:
Women demonstrate a strong interest in additional breast imaging center consultation services regarding imaging results, breast density, and risk assessment, and would prefer to meet with breast radiologists, though are not willing to pay additional fees. Patients were less interested in CBE at the time of mammography, though those that were preferred a breast radiologist.
Clinical Relevance:

Breast centers should consider implementation of consultation services by breast radiologists for issues referring providers may feel less comfortable discussing. Though most patients would not pay for these services, the benefits of engaging patients and increasing visibility of the profession may offset costs, particularly if physician extenders are carefully employed. This is important in a healthcare environment where patients absorb increasing costs and become more discerning about provider choice, and as reimbursements are becoming increasingly linked to patient satisfaction and value provided.

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